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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,357	09/10/2001	Janet A. Warrington	3355.1	9510

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AFFYMETRIX, INC  
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EXAMINER	
MARSCHEL, ARDIN H	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/955,357	WARRINGTON, JANET A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11/18/03, 3/4/04, and 6/14/03.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 3,15,27, & 39 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,4-14,16-26,28-38, & 40-48 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-48 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 18 November 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

### **DETAILED ACTION**

Applicant's election of Specie A in the reply filed on 6/14/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

#### **TITLE**

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to computer software products whereas the instantly elected invention includes methods, a computer readable medium, a system, as well as the computer software products, directed to SNP gene expression comparison.

#### **VAGUENESS AND INDEFINITENESS**

Claims 1, 2, 4-14, 16-26, 28-38, and 40-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 8, cites the phrase "the genes" which lacks clear antecedent basis because the claim lacks a citation of some specific set of genes corresponding to said phrase "the genes". Claim 13, line 9; claim 25, line ; and claim 37, line 12; also contain this unclarity via the phrase "the genes". Clarification via clearer claim wording is requested. Claims which are dependent directly or indirectly from claims 1, 13, 25, or 37 also contain this unclarity due to their dependence.

Claim 1, line 1, indicates that genetic variations are being correlated to gene expression, but confusingly the actual claim steps lack any variation limitation. It may be assumed that the claim citations directed to first and second genotypes are indicative of these genotypes being variants, or at least different in some way, however, no such specific variant or difference limitation is set forth in claim 1 regarding said first and second genotypes. The need to make an assumption as described above supports this rejection in that assuming lacks clarity and conciseness as required under 35 U.S.C. § 112, second paragraph. Claims 13 and 25 also contain this unclarity. Clarification via clearer claim wording is requested. Claims which are dependent directly or indirectly from claims 1, 13, or 25 also contain this unclarity due to their dependence.

#### PRIOR ART

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, and 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroes et al. (P/N 6,194,158).

Kroes et al. summarizes the disclosure therein in the abstract as being directed to characterizing cancer via gene expression. Such gene expression characterization is reasonably a type of gene expression profile as cited in the instant claims. An additional summary paragraph regarding expression of an array of gene signals corresponding to cancer cells is set forth in the reference in column 4, lines 1-18. A

variety of detection methods for such gene expression are summarized in column 7, line 11, through column 8, line 28, wherein monitoring as many as 1000 genes (as in instant claim 6) is described in the bridging sentence between columns 7 and 8. SNP screening as connected with gene under- or over-expression is particularly described in column 9, lines 5-13, corresponding to the elected subject matter of the instant claims. The correlation to SNPs via Table I or SEQ ID Nos. 1-9 in column 9, lines 5-13, is also discussed as being useful in cancer detection as discussed in column 9, lines 14-26. The above summary of SNP (genotype) correlation with gene expression profiles suggests that such correlation has been obtained via a method as instantly claimed wherein gene expression profiles with a first genotype (a first SNP form) and a second genotype (a second SNP form) segregates expression profiles to identify genes therein corresponding to the above Table I or SEQ ID Nos. as claimed in instant claim 1.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to identify SNP correlation(s) or segregation(s) via a plurality of expression profiles as instantly claimed as suggested by the various gene expression profiling descriptions in the reference to result in a reasonable expectation of success of performing the instantly claimed invention. Claims 7 and 8 are included as rejected hereinunder as the repetition of an invention to analyze more genes is deemed generally obvious.

Claims 13, 14, 16-21, 25, 26, 28-33, 37, 38, and 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroes et al. (P/N 6,194,158); taken in view of In re Venner [262 F.2d 91, 95, 120 USPQ 193, 194, (CCPA 1958)].

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Kroes et al. has been summarized above regarding the basic SNP/gene expression profiling of the instant invention but does not describe automation of this methodology such as practicing computer software, media, or systems as cited in the above listed instant claims. In re Venner is a legal decision which indicates that it is obvious to automate a manual activity. Thus, it would have been obvious to practice the Kroes et al. invention via automation such as via computer software, media, and systems as suggested and motivated by In re Venner to result in the practice of the above listed instant claims.

#### **CUMULATIVE CITATIONS**

Iris et al. (P/N 6,403,309) and Henkins et al. (P/N 6,391,558) are cited on the enclosed PTO Form 892 due to both describing polymorphisms correlated with gene expression profiles, however, are cumulative to the above rejection.

#### **INFORMALITIES**

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Note hyperlinks in the specification on page 10, line 4, and page 15, line 31. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim 13 is objected to due to an apparently misspelled word "poduct" in line 1.

Appropriate correction is required.

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No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 29, 2004

*Ardin H. Marschel 9/29/04*  
ARDIN H. MARCHEL  
PRIMARY EXAMINER